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Sustainable Agriculture, Patent Rights, and Plant Innovation

MARK D. JANIS*

INTRODUCTION

To an outsider, "sustainable agriculture" is a loose collection of aspirations whose analytical content has yet to catch up to its considerable rhetorical force. Proponents offer sustainability as the very "organizing theme" upon which other agricultural policies should draw.[1] No standard definition of the concept has emerged,[2] but all rest on basic notions of balance between environmental and economic factors.[3] Some formulate this balance in its broadest social terms. For example, according to the American Society of Agronomy, "[a] sustainable agriculture is one that, over the long term, (1) enhances environmental quality and the resource base on which agriculture depends, (2) provides for basic human food and fiber needs, (3) is economically viable, and (4) enhances the quality of life for farmers and society as a whole."[4]

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1. According to Neil Hamilton, "the concept of sustainability is not a separate item in agricultural policy debates over issues such as price, income support, and international trade. Instead, sustainability should be the organizing theme upon which policies are based and the standard against which their performance is measured." Neil D. Hamilton, *The Role of Law in Promoting Sustainable Agriculture: Reflections on Ten Years of Experience in the United States*, 3 DRAKE J. AGRIC. L. 423, 430 (1998) [hereinafter Hamilton, *Role of Law*].

2. Indeed, the literature contains numerous apologies for the ambiguities that continue to surround the concept of sustainability. *See, e.g.*, Steve Padgitt & Peggy Petrzelka, *Making Sustainable Agriculture the New Conventional Agriculture: Social Change and Sustainability*, *in* SUSTAINABLE AGRICULTURAL SYSTEMS 261, 268-69 (J.L. Hatfield & D.L. Karlen eds., 1994) ("Defining sustainable agriculture is elusive, and probably will remain so. . . . One reason is the inevitable ambiguity that exists in the direction of any social movement."); Neil D. Hamilton, *Sustainable Agriculture: The Role of the Attorney*, 20 ENVTL. L. REP. (Envtl. L. Inst.) 10021, 10022 (1990) ("A major hurdle in the debate over promoting sustainable agriculture is defining the term.").

3. *See, e.g.*, Hamilton, *Role of Law*, *supra* note 1, at 425 ("Sustainable agriculture is defined in various ways, but in its simplest form, it means developing agricultural practices which protect the environment while preserving the economic profitability of farmers."); Neil D. Hamilton, *Feeding our Future: Six Philosophical Issues Shaping Agricultural Law*, 72 NEB. L. REV. 210, 239-40 (1993) (suggesting that sustainability might offer a conceptual basis for a voluntary land ethic that might mollify environmentalists while protecting farm profitability).

4. David C. White et al., *Economics of Sustainable Agriculture*, *in* SUSTAINABLE AGRICULTURAL SYSTEMS, *supra* note 2, at 229, 232; *see also* Neil D. Hamilton, *Agriculture Without Farmers? Is Industrialization Restructuring American Food Production and Threatening the Future of Sustainable Agriculture?*, 14 N. ILL. U. L. REV. 613, 645 (1994) (arguing that "[f]or an agricultural production system to be sustainable it can not just deal with soil and water or price and income, but the system must also consider the farmers, their families, and the rural communities which make up the cultural structure of an agrarian system."). *See generally* MEETING THE

Similarly, Gordon Conway has adeptly captured the exuberance of sustainable agriculture while at the same time recognizing its weakness: "[a]lmost anything that is perceived as 'good' from the writer's perspective can fall under the umbrella of sustainable agriculture: organic farming, the small family farm, indigenous technical knowledge, biodiversity, integrated pest management, self-sufficiency, recycling and so on."[5]

Other, more humble definitions emphasize specific agricultural practices that embody the aspirations of sustainability. For example, sustainable agriculture might be defined in terms of practices such as crop diversification, biological—as opposed to chemical—pest control, and "[g]enetic improvements in crops to resist pests, diseases, and drought and to use nutrients more efficiently."[6]

Even the more constrained, agronomic definitions of sustainable agriculture suggest an interconnection with intellectual property rights. Contemporary crop genetic improvements derive largely from private investment in research and development in both conventional breeding and plant biotechnology. Firms that risk research and development dollars in plant innovation seek a wide array of intellectual property rights in an effort to appropriate maximum returns on their research and development investments.[7] The availability and scope of intellectual property protection for plant innovation may affect the level of private research investment in plant innovation, and may affect the eventual level of user access to the products and processes created in the course of such research. If the creation and utilization of genetic crop improvements is an element of sustainable

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EXPECTATIONS OF THE LAND: ESSAYS IN SUSTAINABLE AGRICULTURE AND STEWARDSHIP (Wes Jackson et al. eds., 1984).

5. GORDON CONWAY, THE DOUBLY GREEN REVOLUTION: FOOD FOR ALL IN THE 21ST CENTURY 163-64 (1997).

6. John Pesek, *Historical Perspective*, *in* SUSTAINABLE AGRICULTURAL SYSTEMS, *supra* note 2, at 1, 14. Sustainable agriculture may be defined by "four broadly accepted elements:"

> (1) prices which cover the full cost of production, including environmental costs and fair income; (2) reduced dependence on chemical fertilizers and pesticides; (3) reduction of externalized ecological impacts through pollution prevention and cost internalization; and (4) greater reliance on the use of ecologically modern farming practices such as integrated pest management (IPM), crop rotations, no-till and reduced tillage systems, and other practices that reduce soil loss and contamination, cut air and water pollution, and avoid losses in habitat and biodiversity.

Mark Ritchie & Kristin Dawkins, *WTO Food and Agricultural Rules: Sustainable Agriculture and the Human Right to Food*, 9 MINN. J. GLOBAL TRADE 9, 21 (2000).

7. For an overview, see Jay P. Kesan, *Intellectual Property Protection and Agricultural Biotechnology: A Multidisciplinary Perspective*, 44 AM. BEHAV. SCIENTIST 464 (2000). *See also* Debra L. Blair, *Intellectual Property Protection and its Impact on the U.S. Seed Industry*, 4 DRAKE J. AGRIC. L. 297 (1999).

agriculture, then the character of applicable intellectual property regimes is necessarily also an element.

The role of intellectual property rights in agriculture has not escaped the attention of policymakers in the agricultural arena. One prominent report warns that "broad intellectual property claims, or claims on DNA sequences without a true invention being made" have the capacity to stifle research and development in plant genetics.[8] Another study identifies "the nature and effect of broad patent claims in agricultural biotechnology" as a major topic for future research.[9] Still other studies place the issue in an international context.[10]

Undoubtedly, agricultural policy scholars will continue to seek out ways to locate intellectual property rights within the framework of agricultural policy and, specifically, the framework of sustainable agriculture. As an intellectual property scholar, however, I am inclined towards taking a reverse perspective, asking how the aspirations of sustainable agriculture might most plausibly find their collective way into the modern intellectual property framework, with particular reference to U.S. patent doctrine. In this essay, I explore two patent law doctrines and analyze whether they are likely to prove effective as vehicles for sustainable agriculture policy initiatives. I first consider the doctrine of subject matter eligibility as applied to plant innovation. Here, I conclude that while proponents of sustainable agriculture may be tempted to support efforts to impose restrictions on patent eligibility for plant innovation, it is very doubtful that any such restrictions would advance a policy agenda embodying sustainable agriculture concepts. I next consider the doctrine of experimental use, a defense to patent infringement—and, as such, a tool for shaping patent scope. I find the experimental use doctrine to be more promising as a policy tool, but I counsel against reliance on traditional judicial or legislative mechanisms for implementing the doctrine, and propose an alternative approach.

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8. ROYAL SOC'Y OF LONDON ET AL., TRANSGENIC PLANTS AND WORLD AGRICULTURE 34 (2000), *available at* http://www.nap.edu/books/NI000227/html (published by the National Academies Press as the product of an inter-academies working group).

9. William Lesser et al., *Intellectual Property Rights, Agriculture, and the World Bank*, *in* INTELLECTUAL PROPERTY RIGHTS IN AGRICULTURE: THE WORLD BANK'S ROLE IN ASSISTING BORROWER AND MEMBER COUNTRIES 1, 10 (Uma Lele et al. eds., 2000).

10. *E.g.*, MAHENDRA SHAH & MAURICE STRONG, FOOD IN THE 21ST CENTURY: FROM SCIENCE TO SUSTAINABLE AGRICULTURE 46-48 (2000) (describing the potential clash of interests between plant breeding firms in the developed world that seek intellectual property rights to secure research and development investments and farmers in the developing world who seek access to improved crop technology).

I. PLANT INNOVATION AND RESTRICTIONS ON PATENT-ELIGIBLE SUBJECT MATTER

The subject matter eligibility provision in U.S. utility patent law designates four broad categories of patent-eligible subject matter: compositions, machines, articles of manufacture, and processes.[11] Plants are not expressly included; no biological subject matter is included by express language. However, in 1980, the Supreme Court construed section 101 to encompass genetically-modified microorganisms.[12] In 1985, the United States Patent and Trademark Office (PTO) applied the same rationale to extend section 101 to seed-grown plants.[13]

The PTO's construction remained unchallenged for several years. Recently, the eligibility issue resurfaced in litigation between Pioneer Hi-Bred and an independent farm supply dealer over the unauthorized sale of hybrid seed corn. The *Pioneer* litigation focuses on the legal issue of whether the existence of an additional form of intellectual property protection for plants (plant variety protection under the Plant Variety Protection Act) signals Congress' intent to exclude plants from the utility patent regime.[14] Both the district court and the Court of Appeals for the Federal Circuit rebuffed the defendant dealer's challenge to the propriety of the PTO's construction of section 101.[15] The case was on review before the U.S. Supreme Court as of the time of this writing, and the forthcoming opinion can be expected to concern itself primarily with this issue. The more important policy issue, however, is whether eligibility restrictions can serve as tools for effectuating agricultural policy initiatives. Specifically, should proponents of sustainable agriculture expect that subject matter eligibility restrictions would be an effective strategy for shaping the utility patent system to respond to the aspirations of sustainable agriculture?[16]

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11. 35 U.S.C. § 101 (1994).

12. *See* Diamond v. Chakrabarty, 447 U.S. 303, 314-18 (1980).

13. *See* Ex *parte* Hibberd, 227 U.S.P.Q. (BNA) 443 (Bd. Pat. App. & Interf. 1985).

14. See *infra* pp. 110-15 for a more detailed explanation of plant variety protection.

15. Pioneer Hi-Bred Int'l, Inc. v. J.E.M. Ag Supply, Inc., 49 U.S.P.Q.2d (BNA) 1813 (N.D. Iowa Aug. 18, 1998), *aff'd*, 200 F.3d 1374 (Fed. Cir. 2000), *cert. granted*, No. 99-1996, 2001 U.S. LEXIS 1696 (Feb. 20, 2001). For relevant commentary on the *Pioneer* case, see Mark D. Janis & Jay P. Kesan, *Weed-Free I.P.: The Supreme Court, Intellectual Property Interfaces, and the Problem of Plants*, 70 U. CIN. L. REV (forthcoming 2001); Mark D. Janis & Jay P. Kesan, *Designing an Optimal Intellectual Property System for Plants: A Supreme Court Debate*, 19 NATURE/BIOTECH. 981 (2001).

The Supreme Court has now affirmed. *See* Pioneer Hi-Bred Int'l, Inc. v. J.E.M. Ag Supply, Inc., 2001 WL 1560870 (Dec. 10, 2001).

16. Preliminarily, one might ask whether eligibility restrictions directed towards plant innovation would violate international obligations. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),

For two major reasons, restrictive patent eligibility rules make especially clumsy policy instruments and should not be made the centerpiece of any effort to inject sustainable agriculture values into the utility patent system. First, experience has demonstrated that eligibility restrictions stimulate counterproductive ancillary litigation over efforts by patent lawyers to draft around the restrictions. Second, whereas policymakers may assume that restricting utility patent eligibility forces innovation into the public domain, the fact is that in some areas of technology—especially plant breeding—restricting utility patent eligibility may simply divert innovation either to less socially desirable intellectual property regimes or to other protection schemes.

A. Drafting Around Eligibility Restrictions

Rules restricting utility patent subject matter eligibility turn out to be clumsy policy instruments. This clumsiness is attributable in part to the subtleties of patent claiming practice.

Utility patents must include one or more claims defining the boundaries of the patented invention.[17] There is no set format for,[18] nor any required number of, claims. Any given utility patent usually includes a number of claims that define the invention in a variety of ways to maximize patent scope while distinguishing the invention from prior art. The precise content of the claims depends in no small part on the patent lawyer's drafting style and judgments about the appropriateness of various claiming approaches.

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which establishes international minimum standards for some substantive elements of patent law, is generally antithetical to the use of subject matter eligibility restrictions to discriminate among technologies. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights [hereinafter TRIPS Agreement], Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81, 94 (1994) ("patents shall be available and patent rights enjoyable without discrimination as to . . . the field of technology. . . ."). However, the TRIPS Agreement makes a special exception from the anti-discrimination principle for plants, authorizing member states to exclude from patent eligibility "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof." *Id.* (further providing for a review of this provision after a specified time).

See *infra* notes 96-97 and accompanying text for a discussion of TRIPS Agreement provisions that might affect an experimental use provision directed to plant innovation. *See generally* S.K. Verma, *TRIPS and Plant Variety Protection in Developing Countries*, 17 EUR. INTELL. PROP. REV. 281 (1995) (discussing relevant TRIPS articles against the backdrop of the International Convention for the Protection of New Varieties of Plants (UPOV) and selected other regimes for plant protection).

17. 35 U.S.C. § 112 (1994).

18. Patent lawyers generally do comply with various drafting conventions that have evolved as a matter of practice, but generally these concern matters of form.

Most of the rules in the utility patent system—including the eligibility rules—are keyed to individual patent claims, not to patents as a whole. For example, a hypothetical rule that "software" is not patent-eligible subject matter would, in actual application, require the decisionmaker to analyze each independent claim in a patent separately, determining whether that claim was directed to "software." In any given patent, it is quite possible that some of the claims define patent-eligible subject matter, while others do not.

Proponents of eligibility restrictions for utility patents on plants should pause to consider how such restrictions would operate when applied to individual claims to plant innovations. Consider, for example, a rule that "plants" are ineligible subject matter.[19] A superficial policy analysis might suggest that such a rule would have major policy ramifications. For example, one can imagine arguments that such restrictions would enhance farmer access to newly-developed crop varieties.

The actual policy outcome would likely be quite different. To apply a "plant" ineligibility rule, the courts or the PTO would need to determine whether individual patent claims are drawn to a "plant" and thus fail to define patent-eligible subject matter. Claims drawn expressly to plants will obviously fall within the rule, but plant innovation may be claimed via a multiplicity of other approaches. Consider the following examples:

(1) seed claim:

> 1. Inbred corn seed designated PHP38, having the ATCC Accession No. 75612.[20]

(2) claim to other plant parts:

> 3. Pollen of the maize plant produced from seed of maize inbred line designated PHKW3 and having ATCC Accession No. 97435.[21]

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19. The Supreme Court has now held in *Pioneer* that the current statutory scheme does not require a plant ineligibility rule. See *Pioneer*, 2001 WL 1560870, at *13. Of course, Congress might be asked to amend the patent statute to incorporate such a rule.

20. U.S. Patent No. 5,506,367 (issued Apr. 9, 1996).

21. U.S. Patent No. 5,534,661 (issued July 9, 1996). Claim 3 of the patent is a dependent claim; I have rewritten the claim for clarity, to incorporate the limitations of the underlying claims.

(3) tissue culture claim:

> 3. A tissue culture of regenerable cells of a plant of the inbred corn line PHKM5 and having ATCC Accession No. 97218 wherein the tissue regenerates plants having all of the physiological and morphological characteristics of PHKM5.[22]

(4) method claim:

> 7. A process to produce a hybrid corn seed which gives rise to a hybrid corn plant having alleles which, when expressed, contribute to hybrids which are adapted to the central corn belt and which exhibit improvement in the traits of: yield, stay green, stalks and roots, compared to similarly adapted hybrids, comprising the steps of:
>
> (a) planting, in pollinating proximity, seed of corn inbred line PHN46 having ATCC accession No. 91733 and another inbred line, not PHN46;
>
> (b) cultivating corn plants resulting from said planting, said corn plants having a male and female reproductive system;
>
> (c) inactivating the male reproductive system prior to pollination of the plants of either the female inbred line;
>
> (d) allowing natural cross pollinating to occur between the inbred lines; and
>
> (e) harvesting seeds produced on said inactivated plants of the inbred line.[23]

(5) product-by-process claim:

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22. U.S. Patent No. 5,491,286 (issued Feb. 13, 1996). As in the preceding example, claim 3 of this patent is a dependent claim; I have rewritten the claim for clarity, to incorporate the limitations of the underlying claims.

23. U.S. Patent No. 5,567,861 (issued Oct. 22, 1996).

> 8. F.sub.1 hybrid corn seed produced by crossing the inbred corn plant PHN46, having ATCC No. 91733, with another corn plant that is not PHN46, and plants and parts thereof produced from the F.sub.1 hybrid seed.[24]

It is not clear whether a rule restricting subject matter eligibility for "plants" would render ineligible any of these example claims. Are plant parts "plants"? Are breeding methods "plants"? And what of claims that are drawn to plants, but crafted in terms of the methods used to breed them—so-called product-by-process claims?

Unfortunately, a broad rule crafted merely to exclude "plants" from utility patent eligibility resolves none of these questions definitively. In applying such a rule, courts and the PTO would face uncomfortable choices. On the one hand, extending the rule to claims that are directed to seeds, pollen, or other plant parts calls for a considerable feat of interpretation. Extending the rule even further—such as to method claims—under the guise of interpretation would seem incongruous. On the other hand, limiting the rule to claims drawn expressly to plants is also problematic, because the rule can be so easily circumvented—simply by formulating claims to seeds or plant parts, for example—that it may be rendered meaningless.

The preceding examples, of course, concern claims to plant innovation resulting from conventional (non-biotech) breeding techniques. The dilemma is even more intractable when the claimed invention concerns transgenic plants, because biotechnology lends itself to an even wider array of potential claiming formulations. For example, as an alternative to claiming the transgenic plant as such, one might draft claims to the plant *cell* as genetically modified,[25] to the plant DNA constituting the modification of interest,[26] or to a tremendous variety of other genetic constructs ordinarily claimed as compositions.[27]

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24. *Id.*

25. For example, a patent relating to Calgene's infamous Flavr-Savr tomato includes claims to a genetically modified plant cell. U.S. Patent No. 4,801,540 (issued Jan. 31, 1989) (stating in claim 14 "[a] tomato plant cell comprising a DNA construct [having specified characteristics set forth in preceding claims]"). Claim 8 called for "a DNA sequence of at least 15 base pairs of a DNA sequence encoding tomato polygalacturonase (PG) joined, in the opposite orientation for expression, 5' to the 3' terminus of a transcriptional initiation region functional in plants." *Id.*

26. Consider the following example relating to a tomato that has been genetically modified to exhibit *Fusarium* resistance:

Ultimately, one must question whether a rule that generically excludes "plants" from patent eligibility achieves socially desirable outcomes. Such a rule is likely to give rise to gamesmanship in the semantics of claim drafting[28] and, as a consequence, is likely to produce a swarm of ancillary litigation over imponderables such as the true meaning of "plant." It seems very unlikely that such a rule would be at all effective in accomplishing ambitious policy goals—unless the goals include diverting resources to ancillary litigation. Indeed, rather than stimulating the patent system to reflect ambitious policy objectives arising from notions of sustainable agriculture, a generic exclusion of plants from patent eligibility seems more likely to divert judicial and PTO resources towards managing a confusion of rules on the scope of the exclusion.

These are not hypothetical debates. Each of the example claims (1) through (5) set out above appears in patents that are in litigation in the *Pioneer* case at the time of this writing.[29] If Congress were to craft a broad "no plants" eligibility restriction, it is very likely that disputes over claiming format, as just described, would quickly arise at the PTO and in the courts.

Of course, it would be incorrect to suggest that a generic exclusion of all "plants" from patent eligibility is the only cognizable eligibility restriction for plant innovation. One could argue that even if there is little to be gained from an apparently sweeping exclusion of all "plants" from the utility patent system, a more focused eligibility restriction excluding claims to "plant varieties" might be more palatable.[30]

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1. An isolated DNA molecule which, when recombinantly transferred into a non-resistant tomato plant, expresses a protein which confers resistance to Fusarium oxysporum f.sp lycopersici race 2, comprising:
   (a) a DNA molecule comprising [a specified nucleotide sequence];
   (b) a DNA molecule capable of hybridization with [the specified sequence under specified conditions], and which encodes a protein which confers resistance to Fusarium oxysporum f.sp lycopersici race 2; or
   (c) a DNA molecule which encodes a protein encoded by the DNA of (a) or (b).

U.S. Patent No. 6,100,449 (issued Aug. 8, 2000).

27. For example, other claims in the *Fusarium*-resistant tomato patent are directed to gene constructs containing the DNA, expression vectors, and so forth. *Id.*

28. On this phenomenon generally, see John R. Thomas, *Of Text, Technique, and the Tangible: Drafting Patent Claims Around Patent Rules*, 17 J. MARSHALL J. COMPUTER & INFO. L. 219, 257 (1998) (exploring strategies for drafting claims to circumvent eligibility restrictions).

29. *See Pioneer*, *supra* note 15.

30. Supporters of such an argument seem to start with the assumption that the protection afforded to plant varieties under the Plant Variety Protection Act duplicates the protection that would be afforded under the utility patent regime. For an explanation of the inaccuracy of this assumption, see *infra* notes 69-92 and accompanying text.

Whatever the apparent allure of such a restriction, however, the realities of patent claiming practice would cast doubt on whether such a restriction is likely to serve as an effective vehicle for policy change. To be sure, a claim directed expressly to an individual plant variety would fail to define patent-eligible subject matter under such a rule. Accordingly, the following claim, for example, would surely be ruled invalid under such a regime: "1. A hybrid maize plant designated 3730 and its parts, representative seed capable of producing said hybrid maize planting having ATCC accession number 209127."[31]

Nevertheless, a claim to a "plant"—that is, a broader claim that encompassed many varieties without specifying any individual variety—would, in all likelihood, survive. For example, it seems quite possible that the following claim to a transgenic corn plant, which is broad enough to cover many individual varieties, would define patent-eligible subject matter under a "plant variety" restriction:

> 1. A fertile transgenic Zea mays plant comprising preselected DNA encoding a seed storage protein, wherein the preselected DNA is expressed so that the level of a seed storage protein amino acid in said transgenic plant is increased above the level in said plant not containing said preselected DNA, and wherein said preselected DNA is heritable.[32]

Perhaps proponents of a "plant variety" restriction would be dubious about the prospect of a court reaching this seemingly illogical outcome. In fact, however, the example describes the current state of the law in Europe. Article 53(b) of the European Patent Convention currently excludes plant varieties from utility patent protection:

> European patents shall not be granted in respect of:
>
> (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.[33]

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31. U.S. Patent No. 5,689,036 (issued Nov. 18, 1997). This is another patent that is at issue in the *Pioneer* litigation, which is discussed at *supra* note 15 and accompanying text.

32. U.S. Patent No. 6,160,208 (issued Dec. 12, 2000).

33. Convention on the Grant of European Patents, Munich, Oct. 5, 1973, *reprinted in* GERALD PATERSON, THE EUROPEAN PATENT SYSTEM 523-24 (1992). In addition to the European patent regime, another principal regime

Applying article 53(b) to modern biotechnological inventions has proven a monumental task for the European Patent Office.[34] While the state of the law as to some types of biotechnological inventions remains unclear, the European Patent Office has now spoken definitively as to the application of article 53(b) to plant innovation. In *Novartis*, the Enlarged Board of the European Patent Office ruled that:

> [A]ccording to Article 53(b) EPC, a patent is "in respect of plant varieties" and shall not be granted if the claimed subject-matter is directed to plant varieties. In the absence of the identification of a specific plant variety in a product claim, the subject-matter of the claimed invention is not directed to a plant variety or varieties within the meaning of Article 53(b) EPC. That is why it is . . . in agreement with the rules of logic that a patent shall not be granted for a single plant variety but can be granted if varieties may fall within the scope of its claims.[35]

The outcome of the eligibility debate in Europe reinforces the point that eligibility restrictions designed to eject "plant varieties" from the utility patent system will do nothing to address perceived problems of claim overbreadth. Such restrictions cannot be relied upon as the centerpiece of a sustainable agriculture-based reform agenda for the U.S. patent system.

Intellectual property scholars may find that the picture painted here—broadly-drawn eligibility restrictions, extensive efforts to draft around the restrictions via particular claim formats, and resultant counterproductive litigation—has an oddly familiar aspect. It should. The U.S. patent system occupied itself for at least three decades with the question of whether computer software inventions should

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for the protection of plant innovation in Europe is the Community-wide system of plant variety protection. Concerning the latter, see generally P.A.C.E. VAN DER KOOIJ, INTRODUCTION TO THE EC REGULATION ON PLANT VARIETY PROTECTION (1997).

34. The celebrated—and seemingly endless—Harvard Onco-mouse decision exemplifies the difficulties. *See* T 19/90, *Harvard/Onco-mouse*, [1990] E.P.O.R. 501 (Tech. Bd. App.).

35. G 01/98, *Novartis II/Transgenic Plant*, [2000] E.P.O.R. 303, 319. The *Novartis* decision superseded the previous authoritative statement on the issue from the Plant Genetic Systems decision of a Technical Board of Appeal of the European Patent Office. *See* T 356/93, *Plant Genetic Systems/Glutamine Synthetase Inhibitors*, [1995] E.P.O.R. 357 (Tech. Bd. App.) (disallowing a claim because it encompassed plant varieties even though it was not drafted in terms of a specific plant variety as such). *See generally* Joshua V. Funder, *Rethinking Patents for Plant Innovation*, 21 EUR. INTELL. PROP. REV. 551 (1999).

qualify as patent-eligible subject matter.[36] One concern that informed early jurisprudence was that a patent claim directed to disembodied software—disembodied, that is, from any particular computer or physical process—was a claim to an "abstract idea."[37] Responding to this concern, the Supreme Court ruled in 1972 that patent claims defined ineligible subject matter if they wholly preempted a mathematical algorithm.[38] There followed several years of judicial and PTO hand-wringing over the true nature of a "mathematical algorithm," producing a convoluted tangle of highly formalistic eligibility rules.[39] Eventually, the Court of Appeals for the Federal Circuit all but abandoned the exercise in *State Street Bank,* holding that software claimed in terms of a programmed computer that produces specified "useful, concrete, and tangible result[s]" defines patent-eligible subject matter.[40]

Recent experience with software-related inventions should inform any current debate over patent eligibility restrictions for plants. The lesson from the software area is quite clear: eligibility restrictions have the potential to work great chaos, but lack demonstrated ability to force major policy reform.

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36. The literature on the patent eligibility of software and business method inventions has become gigantic, and the evolution of the relevant law has been recounted many times over. Within this tidal wave of scholarly production are a few particularly adept summaries of the law. *See, e.g.*, John R. Thomas, *The Patenting of the Liberal Professions*, 40 B.C. L. REV. 1139, 1148-63 (1999); Pamela Samuelson et al., *A Manifesto Concerning the Legal Protection of Computer Programs*, 94 COLUM. L. REV. 2308 (1994); Richard H. Stern, *Tales from the Algorithm War: Benson to Iwahashi, It's Deja Vu All Over Again*, 18 AIPLA Q.J. 371 (1990).

37. Another concern was that granting patent protection to software would be cumulative in view of the availability of copyright protection. This view is remarkably similar to the view that utility patent protection for plants and plant variety protection are cumulative. *See infra* notes 69-92 and accompanying text (discussing differences between the utility patent and plant variety protection regimes).

38. Gottschalk v. Benson, 409 U.S. 63 (1972). In its famous "nutshell," the Court held that:

> It is conceded that one may not patent an idea. But in practical effect that would be the result if the formula for converting BCD [binary-coded decimal] numerals to pure binary numerals [the nature of the invention before the Court] were patented in this case. The mathematical formula involved here has no substantial practical application except in connection with a digital computer, which means that if the judgment below [allowing eligibility] is affirmed, the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself.

Id. at 71-72.

39. A few notable decisions along the way include Diamond v. Diehr, 450 U.S. 175 (1981) (claims to a computer-controlled process defined patent-eligible subject matter); Arrhythmia Research Tech., Inc. v. Corazonix Corp., 958 F.2d 1053 (Fed. Cir. 1992) (claims to a software-implemented method defined patent-eligible subject matter); *In re* Alappat, 33 F.3d 1526 (Fed. Cir. 1994) (en banc) (claims to software, drawn in terms of a programmed general-purpose computer, defined patent-eligible subject matter).

40. State Street Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1373 (Fed. Cir. 1998), *cert denied*, 119 S.Ct. 851 (1999). *State Street* is also well known for its refusal to countenance a special subject matter exclusion for "business method[s]." *Id.* at 1375. The Supreme Court has not spoken on *State Street*'s approach either to software-related inventions generally or to business method inventions particularly.

B. Diverting Plant Innovation to Less Desirable Protection Schemes

The preceding analysis offers a pragmatic perspective on the likely fate of eligibility restrictions when those restrictions are articulated in fairly straightforward ways: proscriptions against eligibility for "plants" or, alternatively, for "plant varieties." But what of addressing the problem in theoretical terms? That is, what if one assumes (contrary to experience) that the courts or Congress could fashion an ideal eligibility standard that would resist efforts at circumvention by claim reformatting and would avoid consuming inordinate litigation resources? Or what if one assumes that the courts or Congress could fashion a standard that approaches more closely the ideal standard than do my examples? Could one then expect to employ such an eligibility restriction as a sustainable agriculture policy tool?

The question is fundamental. A full response cannot yet be given based on the current level of understanding of the economics of intellectual property protection in the plant biotechnology sector. Theoretical and empirical studies that are beginning to appear—predominantly in the agricultural economics literature[41]—will assist in answering the question.

In evaluating such studies, policymakers—whether or not they count themselves among the proponents of sustainable agriculture—must bear in mind the complex interplay between utility patent protection and other forms of protection for plants. Specifically, policymakers must reject analyses that are based on the assumption that by ejecting plants from the utility patent regime (e.g., through a subject matter eligibility restriction), one would direct plant innovation into the public domain, where it will be accessible by all, free of any license fees. Such analyses would exaggerate the social cost of utility patent protection, and thus would exaggerate the social benefit of restricting utility patent protection. Innovators in the plant breeding industry (like innovators generally) will not abandon their innovations to the public as a result of utility patent protection being withdrawn. Instead, innovators will redirect their efforts towards acquiring other forms of protection.

In the plant area, there are a number of additional protection options that are less attractive (from the innovator's perspective) than utility patent protection, but

41. Selected examples include Bonwoo Koo & Brian D. Wright, *Dynamic Implications of Alternative Intellectual Property Rights for Crop Genetic Resources* (June 24, 1999) (on file with Koo, koo@are.berkeley.edu); THE BIOTECHNOLOGY REVOLUTION IN GLOBAL AGRICULTURE: INVENTION, INNOVATION, AND INVESTMENT IN THE CANOLA SECTOR (Peter W.B. Phillips & G.G. Khachatourians eds., 2001).

more attractive than simply dedicating the innovation to the public domain: for example, plant variety protection,[42] trade secret protection,[43] and, for some types of plant innovation, plant patent protection.[44] Moreover, plant breeders may seek protections that do not depend on the intellectual property statutes at all—for example, through the use of genetic use restriction technologies, which may confer sterility or incorporate other genetic mechanisms for controlling expression of various agronomic traits.[45]

Accordingly, it is simplistic—grossly so—to make policy based on the assumption that by restricting utility patent eligibility, one diverts innovation into the public domain. Instead, the more probable outcome of even an "ideal" patent eligibility restriction in the plant area would be to divert innovation into other intellectual property (or non-intellectual property) protection regimes. To the extent that these alternative forms of protection are less desirable from a social standpoint than utility patent protection,[46] the diversion of innovation away from the utility patent system represents a social cost that must be weighed in the balance when policymakers compare the costs and benefits of patent eligibility

42. See *infra* notes 69-92 and accompanying text for a discussion.

43. For the leading decision on trade secret protection for plant genetic information, see Pioneer Hi-Bred Int'l v. Holden Foundation Seeds, Inc., 35 F.3d 1226 (8th Cir. 1994) (decided under Iowa state trade secret law). The patent statute (a federal statute) does not preempt state law trade secret regimes. *See aslo* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974).

44. "Plant patent" protection under U.S. law applies to distinct and new plant varieties that have been asexually reproduced. *See* 35 U.S.C. §§ 161-62 (1994) (setting forth the relevant patentability prerequisites); 35 U.S.C. § 163 (1994 & Supp. V 1999) (establishing that the plant patent owner obtains the "right to exclude others from asexually reproducing the plant, and from using, offering for sale, or selling the plant so reproduced, or any of its parts, throughout the United States, or from importing the plant so reproduced, or any parts thereof, into the United States"); *see also* Imazio Nursery, Inc. v. Dania Greenhouses, 69 F.3d 1560 (Fed. Cir. 1995) (infringement only occurs by actual taking of shoots from the protected plant). The architects of the plant patent regime did not expect it to provide any significant source of intellectual property protection for grain crops. *See* Cary Fowler, *The Plant Patent Act of 1930: A Sociological History of its Creation*, 82 J. PAT. & TRADEMARK OFF. SOC'Y 621 (2000). Experience with the plant patent statute has borne out those predictions.

45. *See* ROYAL SOC'Y OF LONDON ET AL., *supra* note 8, at 32-34. Hybridization is, in effect, another form of "technological" protection for plant innovation because hybrids do not breed true. See Blair, *supra* note 7, at 305-06 for a brief account.

46. Consider, for example, the disclosure of detailed technical teachings. The utility patent regime includes rigorous disclosure requirements and from this standpoint may be more socially desirable than either plant variety protection or trade secret protection, under which technical teachings may (or, in the case of trade secrets, must) remain undisclosed and unavailable for follow-on innovators.

Similar comparisons can be made between utility patent protection and genetic antireplication measures. The latter have social and economic consequences extending far beyond the bounds of the innovation arena. Patent protection may look quite benign when compared to genetic use restriction technologies.

restrictions.[47] At all events, policymakers should refuse to accept any analysis that inflates the social cost of patent protection by assuming that free access is the inevitable outcome of restricting patent eligibility.

II. PLANT INNOVATION AND RESTRICTIONS ON PATENT SCOPE: EXPERIMENTAL USE AS AN EXAMPLE

Whereas the doctrine of patent eligibility is a demonstrably ineffective instrument for shaping the scope of patent protection, many other doctrines are likely to serve better in fine-tuning the patent system in conformity with the principles of sustainable agriculture. Among the candidates are the disclosure requirements,[48] the obviousness doctrine,[49] and the doctrine of equivalents.[50] Another, less prominent doctrine may present some intriguing possibilities in the area of utility patents for plants: the experimental use exception.

The experimental use exception excuses infringement liability for acts that are carried out for purposes of experimentation. The exception might be brought to bear on patented plant innovation in a number of ways. For example, a generic experimental use exception (i.e., one cutting across all areas of patented technology) might be applied, either as a matter of common law, or as matter of hypothetical new legislation. Alternatively, one could envision an experimental use exception that is specific to plant innovation, implemented judicially or legislatively.

The experimental use doctrine has long been the darling of scholars.[51] Unlike patent eligibility rules, the experimental use exception has great potential—in

47. I have not discussed other obvious social costs of restricting patent protection for plants, such as the reduction in private investment in plant innovation. Empirical studies are needed so that an assessment of the magnitude of the reduction can be made.

48. The process has already begun to occur. *See* Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362 (Fed. Cir. 1999) (concluding that claims to antisense technology violated the enablement requirement).

49. 35 U.S.C. § 103 (1994 & Supp. V 1999).

50. See *infra* note 84 for a brief discussion.

51. *See, e.g.*, Richard E. Bee, *Experimental Use as an Act of Patent Infringement*, 39 J. PAT. OFF. SOC'Y 357 (1957). For more recent treatments, see Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1 (2001); Maureen A. O'Rourke, *Toward A Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000); Suzanne T. Michel, Note, *The Experimental Use Exception to Infringement Applied to Federally Funded Inventions*, 7 HIGH TECH. L.J. 369 (1992); Jordan P. Karp, Note, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169 (1991); Steven J. Grossman, Note, *Experimental Use or Fair Use as a Defense to Patent Infringement*, 30 IDEA 243 (1990); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989); Ronald D. Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. PAT. & TRADEMARK OFF. SOC'Y 617 (1985).

theory—to effectuate important policy reforms, because it is a relatively direct mechanism for fine-tuning patent scope. Indeed, a notion of liability-free experimentation is intuitively appealing because it seems consonant with one of the core aspirations of the patent system—to promote the progress of the useful arts by making innovative technical teachings available to the public in the form of the patent's written description (augmented by a deposit of biological subject matter), so that the public can apply the teachings to the development of yet further innovation. No doubt scholars have been attracted to the experimental use doctrine both for its apparent theoretical centrality and for its potential significance for patent policy.

However, as I detail in the following sections, policymakers would do well to approach the doctrine of experimental use with carefully tempered enthusiasm. Neither generic nor plant-specific experimental use rules are likely to serve as effective policy tools if approached through traditional judicial or legislative mechanisms. If the experimental use doctrine is to fulfill its considerable potential as a policy tool, more creative approaches may be required.

A. Drawbacks of Generic Experimental Use Rules

U.S. patent law includes a common law experimental use exception. It is a generic rule of allowable experimentation—that is, it might be applied to plant breeding just as it might be applied to any other area of technical endeavor. It is unlikely, however, that the generic experimental use exception, in either a common law or a legislative manifestation, will emerge as a major force in shaping the scope of patented plant innovation.

1. Frailty of Patent Law's Common Law Experimental Use Doctrine

The common law experimental use exception in U.S. patent law traces back to dicta in two decisions by Justice Story. In *Whittemore v. Cutter,* Story observed that where a patent owner asserted infringement of a patented machine, "it could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiment. . . ."[52] In *Sawin v. Guild,* Story seemed to articulate a two-pronged exception: use of a patented invention "for the mere purpose of philosophical experiment, or to

52. Whittemore v. Cutter, (No. 17,600) 29 Fed. Cas. 1120, 1121 (C.C.D.Mass. 1813).

ascertain the verity and exactness of the specification" was exempt from infringement.[53]

Notwithstanding its long history and the abundance of scholarly attention that it has attracted, the common law experimental use exception has had almost no impact in actual litigated cases. Three conventional explanations deserve consideration. First, some cases in which an alleged infringement is arguably "experimental" involve only minimal recoverable value for the patent owner, and hence are not likely to be litigated to judgment.[54] Second, it may be impossible for courts to disentangle an alleged infringer's commercial motives from his "philosophical" experimental motives. Thus, an unrefined experimental use test along the lines of the Story formulation may constitute an empty gesture on the part of infringement defendants.

Third, the Federal Circuit has approached the experimental use exception restrictively. In *Roche,*[55] the court explained that the philosophical experimentation prong of the experimental use exception is "truly narrow" and applies only where the experimentation is "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[56] Under the Federal Circuit's "truly narrow" approach, the experimental use doctrine does not "allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes."[57]

The Federal Circuit's decision in *Embrex* provides an interesting recent exposition of the doctrine.[58] Defendant Service Engineering had retained a university professor to run tests for the purpose of designing around Embrex's patented method for immunizing chicken embryos in ovo (i.e., in the egg).[59] Embrex asserted patent infringement and won a jury verdict, despite Service's claim of experimental use. On appeal, the Federal Circuit affirmed the judgment as a matter of law.[60] The majority opinion treated Service's commercial

53. Sawin v. Guild, (No. 12,391) 21 Fed. Cas. 554, 555 (C.C.D.Mass. 1813).

54. By "minimal recoverable value," I mean that recoverable damages for past infringement are low, and the value of an injunction against future infringement is also low.

55. Roche Prod., Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858 (1984), *cert. denied*, 469 U.S. 856 (1984).

56. *Id.* at 863.

57. *Id.* (refusing to extend the common law experimental use exception to insulate from infringement the testing of a patented composition in connection with obtaining Food and Drug Administration (FDA) approval to market a generic after patent expiration). The case precipitated the passage of a limited statutory experimental use exception, 35 U.S.C. § 271(e). *See also infra* note 93 and accompanying text.

58. Embrex, Inc. v. Service Engineering Corp., 216 F.3d 1343 (Fed. Cir. 2000).

59. *Id.* at 1346.

60. The Federal Circuit vacated and remanded as to the determination of damages. *Id.* at 1350-51.

motivation as a matter free from any real doubt and, with little additional analysis, found the experimental use assertion lacking.

Judge Rader filed a noteworthy concurring opinion. In Judge Rader's view, the patent law should recognize neither a *de minimis* defense to infringement nor an experimental use exception.[61] As to the latter, Judge Rader took the view that the Supreme Court's pronouncements in *Warner-Jenkinson*[62]—that intent is not an element of infringement—precluded the court from recognizing an intent-based experimental use exception.[63] Judge Rader indicated that, in the alternative, if he were forced to recognize the experimental use exception, he would do so only most grudgingly: "even if the experimental use excuse retains some lingering vitality, the slightest commercial implication will render the 'philosophical inquiry/experimental use' doctrine inapplicable. . . ."[64]

There may be an additional explanation beyond the three offered so far for the relative frailty of the common law experimental use doctrine. It may simply be too difficult to articulate a satisfactory *generic* experimental use rule. That is, perhaps the main lesson to be drawn from the undistinguished history of the generic experimental use exception is not that experimental use is a flawed principle, but that the scope of allowable experimental use is likely to vary greatly depending upon the nature of the patented invention and the nature of the technical field. Scholars and policymakers who advocate a more robust experimental use doctrine might do well to consider how to flesh out the doctrine within a particular technological context.

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61. Concerning a *de minimis* defense—which is often intertwined with an experimental use defense—Judge Rader pointed out that *de minimis* infringement should still constitute infringement but will only give rise to *de minimis* damages for past infringement. *Id.* at 1352-53 (Rader, J., concurring). This argument may underestimate the economic consequences of an infringement determination. While damages for past infringement may be minimal, the economic power of an injunction against future infringement may be substantial.

62. Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co., 520 U.S. 17 (1997).

63. *Embrex, Inc.*, 216 F.3d at 1352-53 (Rader, J., concurring). Judge Rader has an interesting point, but has taken the argument a step further than I would go. Judge Rader seems to be arguing that, because the Supreme Court specifically rejected the argument that proof of the alleged infringer's intent to copy should be an element of the patent owner's infringement case, it must also have rejected the argument that an alleged infringer may assert an affirmative defense built around the alleged infringer's intent to experiment. I am attracted to a less ambitious argument: that the recognition of an intent-based affirmative defense may create a serious tension with the strict liability infringement regime, especially if the intent-based defense is so amorphous that it may be widely applied.

64. *Id.* at 1353 (citing *Roche*, 733 F.2d at 863).

2. Legislating a Generic Form of Experimental Use

The recent legislative record concerning experimental use may reinforce the point that a generic rule on experimental use is destined to remain of very limited utility. In 1990, Congress considered adding a section 271(j) to the patent statute, which would have provided that:

> [I]t shall not be an act of infringement to make or use a patented invention solely for research and experimentation purposes unless the patented invention has a primary purpose of research or experimentation. . . . [I]f the patented invention has a primary purpose of research or experimentation, it shall not be an act of infringement to manufacture or use such invention to study, evaluate, or characterize such invention or to create a product outside the scope of the patent covering such invention [to which subsection (e)(1) applies].[65]

There is little reason to expect that the proposed legislation would have had any greater impact than the existing common law doctrine, given the probable difficulty of establishing that one's making or using is "solely" for research or experimentation purposes, as well as the lack of any detailed standard for determining which activities are experimental.[66] There is also no strong reason to suggest that such legislation could pass today in any event.[67]

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65. PATENT COMPETITIVENESS AND TECHNOLOGICAL INNOVATION ACT OF 1990, H.R. DOC. NO. 101-960, at 55-56 (2d Sess. 1990).

66. The legislative history did supply examples of activity that would have been shielded by such a rule:

> (1) testing an invention to determine its sufficiency or to compare it to prior art; (2) tests to determine how the patented invention works; (3) experimentation on a patented invention for the purpose of improving on it or developing a further patentable invention; (4) experimentation for the purpose of "designing around" a patented invention; (5) testing to determine whether the invention meets the tester's purposes in anticipation of requesting a license; and (6) academic instructional experimentation with the invention.

Id. at 44-45. These examples do go beyond restatement of the general principle of experimental use; however, it may be significant for future legislative efforts that the more detailed enunciation of the standard was relegated to the legislative history.

67. The proposed § 271(j) was reported favorably out of committee. *See* Michel, supra note 51, at 388-89. However, the legislation was never enacted.

B. Plant-specific Experimental Use Rules: Drawbacks of Conventional Judicial and Legislative Approaches

Only rarely have scholars considered the possibility of crafting experimental use standards that are specifically tailored to discrete technological sectors.[68] The issue may well arise in the area of plant innovation, however, because courts (or Congress) may be tempted to borrow experimental use concepts from the Plant Variety Protection Act (PVPA) and use them to formulate a plant-specific experimental use rule for patented plant innovation. The following sections explain why proponents of sustainable agriculture should be skeptical of such an approach.

1. Impropriety of Engrafting the PVPA Experimental Use Provision onto Utility Patent Law

If experimental use is of interest as a policy tool for sustainable agriculture, but the common law experimental use exception in utility patent law is not a satisfactory vehicle, judges and policymakers might be tempted to look outside the utility patent regime to the PVPA,[69] which contains an express statutory experimental use (or "research") exception.[70] Some will undoubtedly argue that if utility patent protection and PVPA protection coexist for plants, the experimental use exception from the PVPA should be engrafted onto the utility patent regime, to the extent that the utility patent regime encompasses plants.

Judges should resist such an argument. While the utility patent regime and the PVPA overlap in their subject matter, they strike very different public/private bargains.[71] The PVPA requires relatively low-quality disclosure as compared to

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68. *But see* Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CAL. L. REV. 1, 29 (2001) (exploring reverse engineering and experimentation defenses in the software patent context); Irving N. Feit, *Biotechnology Research and the Experimental Use Exception to Patent Infringement*, 71 J. PAT. TRADEMARK OFF. SOC'Y 819 (1989).

69. 7 U.S.C. §§ 2321-2583 (1994). There is no indication in the legislative history of the PVPA that Congress anticipated that plant innovation would find its way into the utility patent regime (nor is there any evidence indicating whether Congress would have objected to it). Accordingly, the legislative record appears to be silent on the question of whether Congress would have expected PVPA experimental use notions to be superimposed onto the patent regime for patented plant innovation.

70. 7 U.S.C. § 2544.

71. I cannot offer a full discussion of the issue of overlapping intellectual property regimes in general, or even of the overlap between patent and plant variety regimes, within the space of this essay. The overlap issue manifests itself in many intellectual property contexts. For one recent example, see Traffix Devices, Inc. v. Marketing Displays, Inc., 532 U.S. 23 (2001), which discusses the functionality doctrine in the law of trade dress, implicating the patent/trademark overlap.

the utility patent regime, and in exchange confers relatively low-level protection as compared to the utility patent regime. Simply transposing the experimental use provision from one regime to the other would ignore these differences.

The differences are apparent on the face of the respective statutes.[72] The utility patent regime requires disclosures that comply with the utility,[73] enablement,[74] and written description requirements,[75] among others. In addition, the utility patent regime requires not only that the claimed invention be new (in the sense of being distinct from the statutorily-defined universe of prior art),[76] but also that it be non-obvious.[77]

By contrast, the PVPA does not require applicants to provide an enabling disclosure and includes no comparable written description requirement.[78]

While the U.S. literature on the patent/plant variety overlap is underdeveloped, the issue has been given a fuller airing in Europe. Examples of studies concluding that both types of protection may reasonably be extended include Rainer Moufang, *Protection for Plant Breeding and Plant Varieties: a Frontier of Patent Law*, 23 INT'L REV. INDUS. PROP. & COPYRT. 328 (1992) (criticizing the article 53(b) exclusion); Joseph Straus, *Patent Protection for New Varieties of Plants Produced by Genetic Engineering—Should "Double Protection" be Prohibited?*, 15 INT'L REV. INDUS. PROP. & COPYRT. 426 (1984) (criticizing the notion that patent protection and plant variety protection together constitute "double protection").

72. In *Pioneer*, the Supreme Court briefly compared the two regimes. *Pioneer*, 2001 WL 156870, at *10-11. Beyond this comparison, however, the case law and legislative history provide little assistance on the question of how the utility patent and PVPA regimes interrelate.

73. 35 U.S.C. § 101 (1994) (requiring that inventions be "useful" in order to qualify for patent protection).

74. 35 U.S.C. § 112.

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .

Id.

75. Courts have cited the "written description" language in 35 U.S.C. § 112 to justify a separate written description requirement. The requirement has been applied with particular vigor to biotechnology inventions. *See* Regents of the Univ. of California v. Eli Lilly & Co., 119 F.3d 1559, 1566 (Fed. Cir. 1997); Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615 (1998). For a general criticism, see Mark D. Janis, *On Courts Herding Cats: Contending with the "Written Description" Requirement (and Other Unruly Patent Disclosure Doctrines)*, 2 WASH. U. J.L. & POL'Y. 55 (2000). Patent owners claiming biotechnology inventions routinely deposit samples in publicly accessible depositories in order to facilitate compliance with the written description requirement. *See* 37 C.F.R. §§ 1.801-809 (2000) (governing deposits of biological material).

76. *See* 35 U.S.C. § 102 (1994 & Supp. V 1999) (defining the categories of prior art).

77. 35 U.S.C. § 103(a) (1994 & Supp. V 1999).

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Id.

78. For example, although the PVPA requires applicants to deposit seed, this requirement is not analogous to utility patent law's written description requirement because the PVPA deposit need not be made to a publicly

Similarly, while the PVPA requires varieties to be new, distinct, uniform, and stable,[79] the PVPA includes no non-obviousness requirement. In sum, the PVPA asks far less of applicants than does the utility patent regime.

The PVPA also gives far less protection. Analyzed superficially, the PVPA may appear to confer significant rights; the principal PVPA infringement provision contains language comparable to that of the principal utility patent infringement provision.[80] However, the distinctions between the two regimes far outweigh the similarities.

First, and fundamentally, PVPA protection is protection for a specific variety—i.e., a "plant grouping within a single botanical taxon of the lowest known rank. . . ."[81] This is exceedingly narrow protection—analogous, for example, to limiting the copyright in a novel to the lowest level of abstraction, the entirety of the literal text, word for word.[82] The legislative history reveals that the copyright analogy is especially apt. Congress clearly assumed that the routine

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accessible depository. 7 U.S.C. § 2422(4) (1994); 7 C.F.R. § 97.6(d)(1) (2001) (requiring that "[t]he applicant shall submit with the application . . . at least 2,500 seeds of the viable basic seed required to reproduce the variety" but including no requirement that the deposit be accessible to the public).

79. *See* 7 U.S.C. § 2402(a)(1) (1994 & Supp. V 1999) (establishing the standard for "new" varieties in language reminiscent of statutory bar provisions from utility patent law); § 2402(a)(2) (1994) (establishing the standard for distinctness: the variety is "clearly distinguishable from any other variety the existence of which is publicly known or a matter of common knowledge at the time of the filing of the application"); § 2402(a)(3) (1994) (establishing the standard for uniformity: "any variations are describable, predictable, and commercially acceptable"); § 2402(a)(4) (1994) (establishing the standard for stability: "the variety, when reproduced, will remain unchanged with regard to the essential and distinctive characteristics of the variety with a reasonable degree of reliability commensurate with that of varieties of the same category in which the same breeding method is employed").

80. For the principal PVPA infringement provision, see 7 U.S.C. § 2541(a) (1994 & Supp. V 1999), specifying that infringing acts include, e.g., selling or offering to sell (§ 2541(a)(1) (1994)), importing (§ 2541(a)(2) (1994)), sexually multiplying (§ 2541(a)(3) (1994)), and using (§ 2541(a)(4) (1994)). *Cf.* 35 U.S.C. § 271(a) (1994 & Supp. V 1999) (specifying that infringement of a utility patent occurs in cases of unauthorized selling, offering to sell, making, or using of a patented invention).

81. 7 U.S.C. § 2401(a)(9) (1994) defines "variety" as follows:

> The term 'variety' means a plant grouping within a single botanical taxon of the lowest known rank, that, without regard to whether the conditions for plant variety protection are fully met, can be defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one characteristic and considered as a unit with regard to the suitability of the plant grouping for being propagated unchanged. A variety may be represented by seed, transplants, plants, tubers, tissue culture plantlets, and other matter.

Because PVPA protection is limited to variety protection, innovative plant biotechnology processes cannot be protected under the PVPA. Some observers see this as a serious gap in protection. *See, e.g.*, Geertrui van Overwalle, *Patent Protection for Plants: A Comparison of American and European Approaches*, 39 IDEA J. L. & TECH. 143, 166-68 (1999) (asserting that the failure of plant variety regimes to protect processes is a major indication of the need to extend utility patent protection to plant innovation).

82. For a discussion of the notion of "levels of abstraction" in the law of copyright infringement, see Computer Associates Int'l v. Altai, Inc., 982 F.2d 693, 706-07 (2d Cir. 1992).

form of PVPA infringement would be acts of intentional unauthorized reproduction of protected varieties—i.e., straightforward copying.[83] This regime stands in contrast to the utility patent scheme, which features a strict liability infringement regime and allows peripheral claiming rather than limiting inventors to specific preferred embodiments.[84]

Second, the PVPA contains a multiplicity of additional limitations on, and exemptions from, protectable scope, most of which have no counterparts in utility patent law. One of these, of course, is the experimental use exemption: "The use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute an infringement of the protection provided under this Act."[85] But the experimental use exemption exists alongside several other

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83. Explaining the provision in 7 U.S.C. § 2541(a), which establishes that infringement of a protected variety can occur prior to the issuance of a PVPA certificate where the protected variety is distributed with appropriate notice, the legislative history states that this infringement provision "more resembles copyright law than patent law. Justification for this may be found partly in the fact that infringement is expected almost never to be by independent work, but by willful reproduction starting from the protected variety itself." CONG. REP. NO. 91-1604, at 11 (1970).

84. See *supra* notes 17-18 and accompanying text for an explanation of claiming practices in the utility patent regime. The doctrine of equivalents in utility patent law provides another point of contrast with PVPA law. In utility patent law, an accused device that avoids the literal reach of the claim terms avoids literal infringement, but may still infringe if shown to incorporate equivalent elements. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 40 (1997) (rejecting challenges to the existence of the doctrine of equivalents and concluding that "[t]oday we adhere to the doctrine of equivalents").

The PVPA includes no direct analog to the doctrine of equivalents, although it does include a concept of "essentially derived" varieties, which is likely to operate as a very cramped form of equivalency. PVPA infringement provisions apply equally to "(1) any variety that is essentially derived from a protected variety, unless the protected variety is an essentially derived variety; (2) any variety that is not clearly distinguishable from a protected variety. . . ." 7 U.S.C. § 2541(c) (1994).

The PVPA defines "essentially derived variety" in some detail:

> (A) In General.- The term 'essentially derived variety' means a variety that-
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> (i) is predominantly derived from another variety (referred to in this paragraph as the 'initial variety') or from a variety that is predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety;
>
> (ii) is clearly distinguishable from the initial variety; and
>
> (iii) except for differences that result from the act of derivation, conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.
>
> (B) Methods.- An essentially derived variety may be obtained by the selection of a natural or induced mutant or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, transformation by genetic engineering, or other method.

Id.

85. 7 U.S.C. § 2544 (1994).

exemptions and limitations.[86] For example, the PVPA contains a separate private use provision,[87] a "saved seed" provision,[88] and a potentially wide-ranging compulsory licensing provision.[89] Moreover, the section 2541(a) proscription

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86. Collectively, these provisions implement international obligations under the International Convention for the Protection of New Varieties of Plants (as revised at Geneva on Mar. 19, 1991) (UPOV Publication No. 2221(E)) [hereinafter UPOV]. For example, article 15 of the 1991 text of UPOV establishes the following exceptions to the breeder's right:

> (1) [*Compulsory exceptions*] The breeder's right shall not extend to
> (i) acts done privately and for non-commercial purposes,
> (ii) acts done for experimental purposes and
> (iii) acts done for the purpose of breeding other varieties, and, except where the provisions of Article 14(5) apply, acts referred to in Article 14(1) to (4) in respect of such other varieties.
>
> (2) [*Optional exception*] Notwithstanding Article 14, each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or a variety covered by Article 14(5)(a)(i) or (ii).

Id. art. 15.

87. 7 U.S.C. § 2541(e) (1994) ("It shall not be an infringement of the rights of the owner of the variety to perform any act done privately and for noncommercial purposes.").

88. 7 U.S.C. § 2543 (1994) provides that:

> Except to the extent that such action may constitute an infringement under subsections (3) and (4) of section 2541 of this title, it shall not infringe any right hereunder for a person to save seed produced by the person from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on the farm of the person, or for sale as provided in this section. A bona fide sale for other than reproductive purposes, made in channels usual for such other purposes, of seed produced on a farm either from seed obtained by authority of the owner for seeding purposes or from seed produced by descent on such farm from seed obtained by authority of the owner for seeding purposes shall not constitute an infringement. . . .

For litigation on the predecessor version of the saved seed exemption, see Asgrow Seed Co. v. Winterboer, 513 U.S. 179 (1995).

89. 7 U.S.C. § 2404 (1994) provides a public-interest driven compulsory license:

> The Secretary may declare a protected variety open to use on a basis of equitable remuneration to the owner, not less than a reasonable royalty, when the Secretary determines that such declaration is necessary in order to insure an adequate supply of fiber, food, or feed in this country and that the owner is unwilling or unable to supply the public needs for the variety at a price which may reasonably be deemed fair. Such declaration may be, with or without limitation, with or without designation of what the remuneration is to be; and shall be subject to review as under section 2461 or 2462 of this title (any finding that the price is not reasonable being reviewable), and shall remain in effect not more than two years. In the event litigation is required to collect such remuneration, a higher rate may be allowed by the court.

Under utility patent law, only in the rarest circumstances have courts, by way of declining injunctive relief, effectively granted compulsory licenses based on general notions of the public interest. *See, e.g.*, City of Milwaukee v. Activated Sludge, Inc., 69 F.2d 577, 593 (7th Cir. 1934); *see also* TRIPS Agreement, *supra* note 16 (establishing limitations on compulsory licensing practices in national legislation).

against unauthorized "use"[90] extends only to unauthorized use in "producing" another variety. Use in "developing" another variety, even if unauthorized, is not infringement.[91]

In addition, attempting to inject the PVPA experimental use provision into the utility patent regime is administratively more complex than it would appear on the surface. A PVPA certificate includes no claims defining the scope of the grant; the grant is monolithic, and the experimental use exception derogates from that monolithic grant. By contrast, in the utility patent regime, individual claims define the scope of the grant, and any experimental use exception derogates from individual claims. Accordingly, a rule that the PVPA experimental use exception applies to utility patents on plants leaves many questions unanswered. For example, does the exception apply only to those claims directed to plants? Only to claims directed to plant varieties? To entire patents that contain at least one claim directed to plants or to plant varieties? The same questions about claiming format that bedeviled a restrictive eligibility rule[92] would arise in this context as well.

2. Plant-specific Legislation on Experimental Use: Issues of Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) Compliance

The fact that a judge should not borrow PVPA experimental use concepts and inject them into the utility patent scheme does not end the analysis. Some might argue that Congress should create a plant-specific experimental use provision.[93]

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90. 7 U.S.C. § 2541(a).

91. The legislative history attempts to explain this exceedingly fine distinction and its relationship to the experimental use provision:

> Producing (as distinguished from developing) a hybrid or different variety means that use of the protected variety in producing the commercial class of seed of a variety constitutes infringement. Use of the protected variety as one source of germ plasm to breed a novel variety is permissible. As an example, the use of a protected inbred line of corn to cross it with another inbred line to produce a hybrid for commercial use, or production of a composite variety which is repeatedly reconstituted for commercial sale by intercrossing a set of seed lines one of which is protected, shall constitute an infringement. The use of such inbred line for hybridization with other materials to develop through breeding a novel inbred line as provided in section 114 [7 U.S.C. § 2544, the experimental use provision], however, does not constitute infringement; nor does the production of such new inbred line for the general market constitute infringement.

PLANT VARIETY PROTECTION ACT, H.R. REP. DOC. NO. 91-1605, at 11 (1970).

92. *See supra* Part IIA.

93. Congress has already created a specialized experimental use provision to shield tests conducted "solely for uses reasonably related to" obtaining FDA approval. 35 U.S.C. § 271(e) (1994 & Supp. V 1999). Section 271(e) is an extraordinarily complex (some would say inelegant) component of a delicate legislative compromise and may

One response to such a proposal derives from its international implications. A plant-specific experimental use provision might draw charges that it violates international obligations set out in the TRIPS Agreement.[94] Article 27(1) specifies that patent rights must be "enjoyable without discrimination as to . . . the field of technology. . . ."[95] Article 28 provides that among the patent rights enjoyable are the rights to prevent unconsented making or using, either of which could be implicated by an experimentation exemption.[96]

It is not clear how the TRIPS argument would be resolved for a plant-specific experimental use exemption. Article 27(3)(b) allows members to exclude plants from patent eligibility altogether if they enact a *sui generis* regime for plant variety protection. Some may argue that if member states have the authority to eliminate plants from the utility patent scheme altogether, they necessarily have the lesser authority to place plant-specific limitations on the utility patent right. Additional arguments may draw on article 30, under which members may provide "limited exceptions to the exclusive rights conferred by a patent" under specified conditions.[97] The reach of article 30 is not currently clear. Similar questions have surrounded the surgical methods exemption of 35 U.S.C. § 287(c).[98]

C. An Alternative Approach: Informal Breeders' Guidelines?

If conventional judicial and legislative approaches to various experimental use rules are unlikely to yield satisfactory results, it may seem to follow that the experimental use doctrine should be discarded as a serious candidate for balancing private rights against public access in plant innovation. But before turning away to more promising alternatives, policymakers might wish to consider whether a

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not serve well as a model for other technology-specific experimental use provisions. *See, e.g.*, Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 679 (1990) ("No interpretation we have been able to imagine can transform § 271(e)(1) into an elegant piece of statutory draftsmanship.").

94. *See* TRIPS Agreement, *supra* note 16.

95. *Id.*

96. Specifically, article 28(1)(a) of the TRIPS Agreement provides that "(1) A patent shall confer on its owner the following exclusive rights: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product. . . ." *Id.* at 94.

97. In particular, article 30 of the TRIPS Agreement provides that limited exceptions are allowable "provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." *Id* at 95.

98. *See* Cynthia M. Ho, *Patents, Patients, and Public Policy: An Incomplete Intersection at 35 U.S.C. § 287(c)*, 33 U.C. DAVIS L. REV. 601, 653-73 (2000).

non-traditional approach to the experimental use question might be worth pursuing.

The allowable scope of experimental use in a given technology sector may turn out to be more a matter of industry custom than patent law doctrine. If that is so, perhaps some thought should be given to articulating the relevant customs in the plant breeding industry and recording them in the form of a set of informal breeders' guidelines on the allowable use of patented plant inventions. It would be interesting to consider whether, for example, the organized bar, acting with industry and government participation, could arrive at a detailed statement of research norms that would provide reasonable guidance to researchers without seriously impairing the value of patent rights.

No doubt there are many objections to this proposal as well. Some may question whether any set of circumstances could be imagined under which the plant breeding industry would agree to participate in such an effort.[99] Others, no doubt, would scrutinize any agreed guidelines closely for evidence of anticompetitive collusion.[100] Still others may wonder whether the phenomenon of patenting plant innovation is so new that customs are still evolving.

Nevertheless, even if discussions over the scope of allowable experimental use in the plant breeding area failed to result in the drafting of specific guidelines, it still may be a discussion worth having. At the very least, it could serve as the beginning of a constructive dialogue that might hasten the emergence of articulable norms to guide researchers in future plant biotechnology experimentation. Proponents of sustainable agriculture who seek to make the utility patent system more responsive to sustainable agriculture policy initiatives should support such a dialogue.

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99. On this point, it may well be that industry would rather participate in formulating the relevant standards than have them imposed from without, as may be the case if the PVPA experimental use provision is engrafted onto the patent statute.

100. Government participation in the formulation of any such guidelines would be important to insulate against any such charges. In any event, it should not be difficult to distinguish between legitimate cooperation on the one hand, and, on the other, a horizontal agreement among plant biotechnology firms suppressing competition. On the latter issue, see generally HERBERT HOVENKAMP ET AL., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW (2002) (discussing horizontal restraints in intellectual property licensing).